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SECTION 6
510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4359
Fax: 508-683-5939

Contact: Ashley Pyle
Regulatory Affairs Specialist
Date Prepared: December 9, 2008

2. Device

Trade Name: SpyScope Access and Delivery Catheter
Common Name: Catheter
Classification Name: Endoscope and Accessories
Regulation Number: 876.1500
Product Code: KOG
Classification: Class II

3. Predicate Devices

SpyScope Access and Delivery Catheter, K051504
Wilson-Cook Pancreatic Wedge Stents, K990130
Olympus (SwingTip) Disposable Bending Cannula PR-233Q, K011149
SpyGlass Direct Visualization Probe, K052194
Olympus XCHF-BP160F Choledochoscope, K051886

4. Device Description

The SpyScope Access and Delivery Catheter is a sterile, single-use device comprised of two main components: a flexible delivery catheter and a handle. The device is designed to guide the SpyGlass Direct Visualization Probe or other visualization devices and accessory devices, (such as biopsy forceps, cytology brushes, stone retrieval baskets, etc.) during endoscopic retrograde cholangiopancreatography (ERCP) procedures. The SpyScope Access and Delivery Catheter is introduced to the desired anatomical location through a duodenoscope with a minimum working channel diameter of 4.2mm.

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5. Indication for Use:

The SpyScope Access and Delivery Catheter is intended to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

6. Technological Characteristics:

The proposed SpyScope Access and Delivery Catheter has identical technological characteristics (materials, construction, and manufacturing processes) as the currently marketed SpyScope Access and Delivery Catheter.

7. Performance Data:

As this is a request for an expanded indication and introduces no new materials or design changes, performance testing was not repeated to support this submission. Comparison to predicate devices will be used in support of the proposed indication.

8. Conclusion:

Boston Scientific has demonstrated that the proposed SpyScope Access and Delivery Catheter is substantially equivalent to the design of Boston Scientific Corporation's currently marketed SpyScope Access and Delivery Catheter. Boston Scientific is demonstrating substantial equivalence to the proposed anatomical location by comparing the proposed device to BSC SpyGlass Direct Visualization Probe, Wilson Cook's Pancreatic Wedge Stent, the Olympus XCHF-BP160F Choledochoscope, and the Olympus (SwingTip) Disposable Bending Cannula PR-233Q.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

Boston Scientific Corporation
% Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 E. Auora Road, Unit B7
TWINSBURG OH 44087

Re: K090170
Trade/Device Name: SpyScope Access and Delivery Catheter
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODF
Dated: January 22, 2009
Received: January 23, 2009

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

Indications for Use:

510(k) Number (if known): **To Be Determined** K090170

Device Name: **SpyScope Access and Delivery Catheter**

Indications for Use:

The SpyScope Access and Delivery Catheter is intended to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Part D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K090170